K071190

510(k) SUMMARY

J. MORITA USA Inc.'s
ROOT ZX II

AUG 17 2007

1. NAME OF DEVICE

Common/Usual Name: Dental root canal measuring and treatment units
Trade or Proprietary Name: ROOT ZX II
Product Model Name : DP-ZX-VL

2. Submitter Name and Address with Phone/Fax :

Registration No. 2081055	Registration No. 3002807636
Initial Distributor:	Manufacturer:
J. Morita USA, Inc.	J. MORITA MFG. CORP.
9 Mason	680 Higashihama Minami-cho
Irvine, CA 92618	Fushimi-ku, Kyoto
USA	Japan 612-8533
Telephone: 949-581-9600	+81-75-611-2141
Facsimile: 949-581-9688	+81-75-605-2354

3. Contact Person

Keith A. Barritt
Fish & Richardson P.C.
1425 K Street, N.W.
Suite 1100
Washington, DC 20005
Phone: (202) 783-5070
Facsimile: (202) 783-2331

4. Date summary prepared: April 24, 2007

5. DEVICE CLASSIFICATION/CLASSIFICATION PANEL

The DP-ZX-VL is classified as non-exempt Class II device, as
Regulation Number (Regulation Name):
21 CFR § 872.4200(Dental handpiece and accessories) and
21 CFR § 872.6070 (Ultraviolet activator for polymerization).
Regulatory Class : II
Product Code: EKX, LQY and EBZ
Classification Panel: 872 Dental.

6. DEVICE DESCRIPTION/SUBSTANTIAL EQUIVALENCE

DEVICE DESCRIPTION

The DP-ZX-VL is a dental device, built up simply by adding the same function as VL-7 (K063529) to the DP-ZX (K031204) . There are almost no new differences created in functions and structures.

The DP-ZX-VL is composed of a Canal Measurement Module and a Handpiece / LED Module.

The Canal Measurement Module can be used alone and has root canal measurement capability.
The Handpiece / LED Module can be used only when it is connected with the Canal Measurement Module. When it is connected, it has root canal measurement, canal-preparation and light cure functions.

The Canal Measurement and the Canal Preparation functions of the DP-ZX-VL are substantially equivalent to the functions of the DP-ZX (K031204).
The Light Cure function of DP-ZX-VL is the additional function to the DP-ZX (K031204).

SUBSTANTIAL EQUIVALENCE

The DP-ZX-VL is substantially equivalent to other legally marketed devices.

1) Predicate device I : DP-ZX(K031204)
The Canal Measurement and Canal Preparation function of the DP-ZX-VL is substantially equivalent to those functions of the DP-ZX(K031204) from J.MORITA MFG.CORP. The DP-ZX-VL has similar general intended uses, similar principles of operation, and similar technological characteristics to the predicate device, DP-ZX (K031204).

2) Predicate device II : VL-7 (K063529)
The Light Cure Function of the DP-ZX-VL is substantially equivalent to the function of VL-7 (K063529) from J.MORITA MFG.CORP. The DP-ZX-VL has similar general intended uses, similar principles of operation, and similar technological characteristics to the predicate device, VL-7.

Although there are minor differences in the characteristics of the DP-ZX-VL and its predicate devices, these differences do not raise new questions of safety or effectiveness.

Table- 1 Comparison summary table

	Predicate device	
TECHNOLOGICAL CHARACTERISTICS of DP-ZX-VL	**DP-ZX (K031204)**	**VL-7 (K063529)**
Indication for use Canal Measurement Function Canal Preparation Function	Identical	
Light Cure Function		Identical
Target population	Identical	Identical
Design	Identical	Similar
Materials	Identical	Identical
Performance Canal Measurement Function Canal Preparation Function	Similar	
Light Cure Function		Similar
Sterility	Identical	Identical
Biocompatibility	Identical	Identical
Mechanical safety	Identical	Identical
Chemical safety	Identical	Identical
Anatomical sites	Similar	Similar
Human factors	Similar	Similar
Energy used and/or delivered	Similar	Similar
Compatibility with environment and other devices	Similar	Similar
Where used	Identical	Identical
Standards met	Identical	Identical
Electrical safety	Identical	Identical
Thermal safety	Identical	Identical

7. Indications for Use

DP-ZX-VL is a dental device, composed of a "Canal Measurement Module" and "Handpiece / LED Module".

The former can measure the length of the root canal.
The latter can enlarge the root canal while monitoring the position of the file tip inside the canal, and can be used to polymerize (set) resinous and other materials by light from the Light Cure Handpiece head.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

J. Morita USA, Incorporated
C/O Mr. Keith A. Barritt
Attorney
Fish & Richardson P.C.
1425 K Street NW, Suite 1100
Washington, DC 20005

AUG 17 2007

Re: K071190
Trade/Device Name: DP-ZX-VL is a Dental Device, Composed of a "Canal Measurement Module" and "Handpiece / LED Module"
Regulation Number: 872.6070
Regulation Name: Ultraviolet Activator for Polymerization
Regulatory Class: II
Product Code: EBZ, LQY, EKX
Dated: August 14, 2007
Received: August 15, 2007

Dear Mr. Barritt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): unknown

Device Name: ROOT ZX II

Indications For Use: DP-ZX-VL is a dental device, composed of a "Canal Measurement Module" and "Handpiece / LED Module".

The former can measure the length of the root canal. The latter can enlarge the root canal while monitoring the position of the file tip inside the canal, and can be used to polymerize (set) resinous and other materials by light from the Light Cure Handpiece head.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runyon

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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